## **CLAIMS:**

 $e^{2^{2}}$ 

- 1. Water soluble particles of less than 50 μm comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon.
- 5 2. Water soluble particles according to claim 1 wherein the coprecipitant is partially or substantially crystalline.
  - 3. Water soluble particles according to claim 1 wherein the dehydrated biological macromolecule is selected from peptides, polypeptides, proteins and nucleic acid.
  - 4. Water soluble particles according to claim 1 having a diameter less than 10 μm.
- 5. Water soluble particles according to claim 1 wherein the coprecipitant is selected from inorganic salts, sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, for example trehalose, with a molecular weight of less than 10,000 Da; amino-acids such as glycine and arginine;
- 20 acid-base buffers;

  zwitterionic compounds;

  organic salts;

  compounds containing multiple basic groups;

  compounds containing multiple acidic groups;
- 25 bile salts;



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water soluble dyes;
polar or ionic polymers; and
polar or ionic dendrimers.

- 6. A method of preparing water soluble particles comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon comprising the steps of:
- a) preparing an aqueous solution comprising a coprecipitant and a biological macromolecule;
- b) rapidly admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and bioactive molecule immediately coprecipitate from solution forming said particles; and
  - c) isolating said particles from the organic solvent.
- 7. The method according to claim 6 wherein the aqueous solution comprising
  the coprecipitant and the biological macromolecule is prepared by dissolving the
  coprecipitant in an aqueous solution comprising the biological macromolecule.
  - 8. The method according to either of claims 6 or 7 wherein the biological macromolecule/coprecipitant solution is added to the water miscible organic solvent.

9. The method according to claim 6 wherein the coprecipitant:biological macromolecule molar ratio is greater than 50.

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The method according to claim 6 wherein the coprecipitant is selected 10. from inorganic salts; sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, for example trehalose, with a molecular weight of less than 10,000 Da; 5 amino-acids; acid-base buffers; zwitterionic compounds; organic salts; compounds containing multiple basic groups; 10 compounds containing multiple acidic groups; bile salts; water soluble dyes; polar or ionic polymers; and polar or ionic dendrimers. 15

- 11. The method according to claim 6 wherein the organic solvent is selected from methanol, ethanol, propanol, acetonitrile tetrahydrofuran and acetone.
- 20 12. Particles obtainable by the process according to claim 6.
  - 13. A pharmaceutical formulation comprising particles according to claims 1 or 12 and a suitable carrier therefore.

- 14. A medical device comprising particles according to claims 1 or 12 associated therewith.
  - 15. Particles according to claims 1 or 12 for use in therapy.
- 16. A biocatalyst preparation comprising particles according to claims 1 or 12 associated therewith.
- 17. A cleansing agent comprising enzyme coated particles according to claims

  10 1 or 12.
  - 18. A protective or antifouling agent comprising particles according to claims

    1 or 12 in association with paint, varnish, coatings or films.
- 15 19. Films, polymers, inks, coatings, electrodes and optical materials for diagnostic kits or biosensor applications, comprising particles according to claims 1 or 12.
- 20. A method for studying molecular recognition, molecular binding,
   20 molecular imprinting or inhibitor binding in non-aqueous media, comprising using particles according to claims 1 or 12.
  - 21. A method for studying macromolecule structure and/or organisation by scanning probe microscopy, comprising using particles according to claims 1 or 12.

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- 22. A method of isolating a biological macromolecule from an aqueous solution, comprising the steps of:
- a) preparing an aqueous solution comprising a mixture of a coprecipitant and biological macromolecule to be isolated; and
- b) admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and biological macromolecule immediately coprecipitate from solution, with rapid simultaneous dehydration of the biological macromolecule.
  - 23. Water soluble particles of less than 50 μm comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon obtainable by:
  - a) preparing an aqueous solution comprising a coprecipitant and biological macromolecule; and
  - b) admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and biological macromolecule immediately coprecipitate from solution forming said particles; and
    - c) isolating said particles from the organic solvent.
  - 24. Biological macromolecule coated micro-crystals comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon wherein the coprecipitant is selected from inorganic salts, sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, for example trehalose, with a molecular weight of less than 10,000 Da; amino-acids such as glycine and arginine;
- 25 acid-base buffers;

zwitterionic compounds;

organic salts;

compounds containing multiple basic groups;

compounds containing multiple acidic groups;

5 bile salts;

water soluble dyes;

polar or ionic polymers; and

polar or ionic dendrimers.

25. A pharmaceutical formulation comprising biological macromolecule coated micro-crystals comprising a coprecipitant cover with a dehydrated pharmaceutically active biological macromolecule coated thereon wherein the coprecipitant is selected from inorganic salts, sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, for example trehalose, with a molecular weight of less than 10,000 Da;

amino-acids such as glycine and arginine;

acid-base buffers;

zwitterionic compounds;

organic salts;

20 compounds containing multiple basic groups; compounds containing multiple acidic groups; bile salts;

water soluble dyes;

polar or ionic polymers; and

25 polar or ionic dendrimers; and a suitable carrier therefore.

- An inhalable pharmaceutical formulation comprising biological macromolecule coated micro-crystals comprising a coprecipitant core with a dehydrated pharmaceutically active biological macromolecule coated thereon.
- 5 27. Water soluble particles of less than 50 μm comprising a coprecipitant partially, substantially or crystalline core with a dehydrated biological macromolecule coated thereon.
- Water soluble particles comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon, wherein the coprecipitant is selected from ionic salts, amino acids, zwitterionic compounds, organic salts, sugars and polysaccharides of a molecular weight of less than 10,000 Da.
  - 29. Water soluble particles according to claim 28 wherein the coprecipitant has a molecular weight of less than 1,000 Da.
    - Water soluble particles comprising a coprecipitant core coated with a dehydrated biological macromolecule wherein the coprecipitant has a melting point at atmospheric pressure greater than 95° C.
    - 31. A liquid suspension comprising water soluble particles comprising a coprecipitant core coated with a biological macromolecule.
- 32. A method of purifying a biological macromolecule from additives or impurities comprising:

- a) dissolving a coprecipitant in an aqueous solution comprising the biological macromolecule and additive or impurity;
- b) admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent or solvents, in which the additive or impurity is soluble, such that the coprecipitant and biological macromolecule immediately coprecipitate from solution forming a biological macromolecule coated particle comprising a core of coprecipitant;
  - c) rinsing said particles with fresh water-miscible organic solvent; and
  - d) isolating said particles.